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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,020	09/21/2001	Christopher McDowell	COD-133	7026
27777	7590	09/12/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PICKETT, JOHN G	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/960,020

Applicant(s)

MCDOWELL, CHRISTOPHER

Examiner

Gregory Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,8,9,11,12 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,8,9,11,12 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This Office Action acknowledges the applicant's amendment submitted 1 July 2005. Claims 1, 3, 6, 8, 9, 11, 12, and 16 are pending in the application. Claims 2, 4, 5, 7, 10, and 13-15 have been canceled.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 103*

3. Claims 1, 3, 6, 8, 9, 11, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholson et al (US 5,968,044) in view of Asa et al (US 6,098,802) and Nguyen et al (US 5,873,462).

Regarding claim 1, Nicholson et al discloses a surgical fastener (**10**, **34**, and **70**) in the form of a disposable portion (**100**, see Col. 16, lines 2-10). Nicholson et al suggests placement of the surgical fasteners in a sterile tray (see for example, Col. 3, lines 37-38) but does not disclose the structure of said tray.

Both Asa et al and Nguyen et al disclose trays for the sterile storage of disposable portions (see for example, Asa Col. 1 line 17, and Nguyen Col. 2, lines 54-56).

Asa et al discloses a tray **10** with a base **12**, a plurality of wells **18**, a plurality of articles **P** disposed in the wells **18**, and a film **30**. Asa et al teaches the isolated wells to prevent cross-contamination.

Nguyen et al discloses tray **10** with a base **30**, a plurality of wells **31**, a plurality of articles **100** disposed in the wells **31**, and a film **150**. Nguyen et al anticipates scoring of the film **150** to allow for the controlled breaking of the film (see for example, Col. 3, lines 57-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the disposable surgical fastener assemblies of Nicholson et al in a tray as taught by either Asa et al or Nguyen et al in order to provide for independent dispensing of the fasteners.

The assembly of Nicholson-Nguyen discloses the claimed invention.

The assembly of Nicholson-Asa discloses the claimed invention except for the weakness in the film. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the film of Nicholson-Asa with scoring as taught by Nguyen et al in order to control the breakage of the film.

As to claim 3, the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen disclose scoring (see Nguyen, Col. 3, lines 57-63).

As to claim 6, the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen disclose scoring (see Nguyen, Col. 3, lines 57-63) as an ingress means.

Regarding claims 8 and 9, both of the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen, as applied to claim 1, disclose the provision of the tray, the provision of the fastener, the covering of the well, and the modification of the film by presentation.

As to the sterilization, both Asa et al and Nguyen et al disclose sterilization (see for example, Asa, Col. 5 line 65 to Col. 6, line 7, and Nguyen Col. 3, lines 46-50) and it

would have been obvious to one of ordinary skill in the art at the time the invention was made to include this feature for the assemblies either of Nicholson-Asa-Nguyen or Nicholson-Nguyen since the fasteners of Nicholson-Asa-Nguyen and Nicholson-Nguyen are to be used in a surgical procedure.

As to the penetration of the film, both Asa et al and Nguyen et al disclose accessing the articles by penetration of the film with an instrument (see Asa Figure 6, and Nguyen, Col. 3, lines 57-67).

As to claims 11 and 12, the assemblies of Nicholson-Asa-Nguyen and Nicholson-Nguyen disclose scoring (see Nguyen, Col. 3, lines 57-63).

As to claim 16, both Asa et al and Nguyen et al disclose accessing the articles by penetration of the film with an instrument (see Asa Figure 6, and Nguyen, Col. 3, lines 57-67). Both Asa et al and Nguyen et al form assemblies with the articles and instruments, which are necessary for their intended use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to penetrate the film of the assemblies of Nicholson-Asa-Nguyen or Nicholson-Nguyen with the applier (Nicholson 120) as taught by both Asa et al and Nguyen et al in order to form an assembly for the application of the fastener.

### ***Response to Arguments***

4. Applicant's arguments filed 1 July 2005 have been fully considered but they are not persuasive. While Nicholson et al does disclose a preferred embodiment wherein the tray holds the fasteners in addition to other components of the assembly, this does

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not detract from the fact that disposable cartridges are also disclosed (see for example, Col. 16, lines 2-10). And it is in this specific embodiment that the examiner has looked to the teachings of Asa and Nguyen for the individual dispensing of the cartridge devices. As duly noted by the applicant, Asa teaches isolated wells in the tray to prevent cross-contamination and Nguyen teaches scoring of the film in addition to isolated wells. The examiner, therefore, maintains that the references of Nicholson et al, Asa et al, and Nguyen et al, when taken as a whole, renders the claimed invention obvious.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

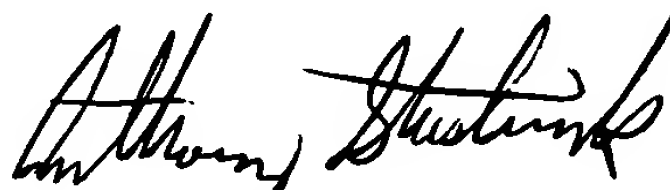
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 571-272-4560. The examiner can normally be reached on Mon-Fri, 11:30 AM - 8:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Greg Pickett  
Examiner  
6 September 2005

  
ANTHONY D. STASHICK  
PRIMARY EXAMINER